FDA Approves First Gene Profiling Test for Cancer

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The Food and Drug Administration (FDA) just approved a first-of-its kind test that can look for mutations in hundreds of cancer genes at one time and ultimately give cancer patients and their providers a more complete picture of what's driving their disease and which treatments may be most appropriate, ABC News reports.

Developed by Foundation Medicine, the test is designed for patients with advanced or widely spread cancers and will make gene profiling of tumors available to far more cancer patients than ever before. According to the announcement, the Centers for Medicare and Medicaid Services (CMS) has already proposed covering the test for patients in state-run insurance programs across the country.

Currently, patients can get tested for individual cancer genes if a drug is available to target those mutations. However, cancer experts say it's a hit-and-miss approach that often leads to unnecessary biopsies and wasted time. The FoundationOne CDx, on the other hand, is capable of surveying 324 genes at once and can help predict success with treatments for a wide range of cancers, including those of the prostate, breast, cancer and lungs.

FDA regulators also noted that the new test would be able to help more patients find and enroll in clinical studies of new, experimental therapies for their cancers if no treatment is currently available for their condition.

Moving forward, CMS says public comments on the coverage proposal for this new cancer test will be taken for 30 days. A final decision is expected early next year, which, if approved, would be followed by setting a price for reimbursement.

Coverage is currently proposed for patients with recurrent, widespread or advance-stage cancers, people who have decided to seek further treatment with their doctors and those who have not yet had a gene-sequencing test. Analysts say if CMS covers the Foundation One CDx test, private insurers will likely follow.